DEC 2 0 2013

K133569

510(k) Summary

Submitter:	Loma Vista Medical 863A Mitten Road, Suite 100A Burlingame, CA 94010 Phone: (650) 490-4747 Fax: (480) 449-2546 Email: chris.timmons@crbard.com
Contact Person:	Tiffini Diage 1307 South Mary Avenue, Suite 280 Sunnyvale, CA 94087 Phone: (707) 799-6732 Fax: (408) 462-9132 Email: tdiage@namsa.com
Date Prepared:	12/20/2013
Trade Name:	True Dilatation Balloon Valvuloplasty Catheter
Classification:	Class II Balloon Aortic Valvuloplasty 21 CFR 870.1250
Product Code:	OZT
Predicate Device(s):	The subject device is equivalent to the following devices: True Dilatation Balloon Valvuloplasty Catheter, 510(k) number K121083
Device Description:	The True Dilatation Catheter is a coaxial catheter with a balloon fixed at the tip used for Balloon Aortic Valvuloplasty (BAV) of the aortic valve. The effective length of the catheter is 110 cm and it has two lumens: one lumen is used to inflate and deflate the balloon and the other permits the use of a guidewire to position the catheter. The balloon inflation luer-lock hub (angled) connects to a syringe inflation device to deliver radiopaque contrast media for inflation. The guidewire luer-lock hub (straight) connects to the guidewire lumen. The balloon functions by connecting an inflation device to the angled luer lock and injecting contrast/sailine into the inflation lumen; which inflates the balloon on the distal end of the catheter. The inflation device plunger is pulled back to deflate the balloon and it can then be withdrawn into the introducer for removal.
Indication for Use:	The True Dilatation Catheter is indicated for balloon aortic valvuloplasty.
Technological Characteristics:	The True Dilatation Balloon Valvuloplasty Catheter in this submission is identical to the previously cleared device. The technical characteristics are the identical. The only change being made in this submission is the addition of the 26mm

balloon diameter size. The product line has been extended to offer 20mm, 22mm, 24mm, and 26mm size balloons. The following technical characteristics are unchanged and identical to the previously cleared product.

Balloon Length	4.5cm
Materials	Shaft: Pebax Balloon: Polymer composite Image Band: Platinum
Recommended Inflation Pressure	3 – 6 ATM
Diameter Variation over Operating Pressure Range	20mm: <2% 22mm: <2% 24mm: <2% 26mm: <2%
Marker Band Locations	1 at proximal balloon shoulder 1 at distal balloon shoulder
Sterilization Method	Ethylene Oxide

Functional and Safety Testing:

To verify that the device design met its functional and performance requirements, representative samples of the device underwent biocompatibility, sterility, packaging integrity, and mechanical testing in accordance with ISO 10993-1 2009, ISO 11135-1 2007, ASTM D4169:2009, ISO 10555-1 2009. The following mechanical tests were performed:

- Dimensional verification of inflated balloon
- Simulated use for access to annulus, inflation, re-sheathing, and withdrawal
- Inflation and deflation time
- Rupture, herniation, and leaking
- Compatibility with introducer

Conclusion:

Loma Vista Medical considers the True Dilatation Catheter to be substantially equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, performance requirements, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 20, 2015

Bard Peripheral Vascular Inc.
Ms. Tiffini Diage
Medical Research Manager
NAMSA
863A Mitten Road, Suite 100A
Burlingame, CA 94010

Re: K133569
Trade/Device Name: True Dilation Balloon Valvuloplasty Catheter
Regulation Number: 21 CFR 870.1255
Regulation Name: Balloon Aortic Valvuloplasty
Regulatory Class: Class II
Product Code: OZT
Dated: November 18, 2013
Received: November 25, 2013

Dear Ms. Diage:

This letter corrects our substantially equivalent letter of December 20, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Nicole G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Appendix 5: Indications for Use

Indications for Use Statement

510(k) Number: K133569

Device Name: True Dilatation Balloon Valvuloplasty Catheter

Indications for Use:

The True Dilatation Balloon Valvuloplasty Catheter is indicated for balloon aortic valvuloplasty.

Prescription Use ___X___ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)